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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/623,970 | 12/28/2000 | Isao Karube | 201487/1030 | 1866 |

7590

05/07/2002

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EXAMINER

LOEB, BRONWEN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 05/07/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,970

Applicant(s)

KARUBE ET AL.

Examiner

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-24 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendment of 14 February 2002 in which claims 2-5 were cancelled and new claims 21-24 were presented.

Claims 1 and 6-24 are pending.

Election/Restrictions

1. Claims 7-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.
2. This application contains claims 7-20 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Amendment

3. The rejection of claims 1-6 under 35 USC §112, second paragraph as being indefinite has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-6 under 35 USC §102(b) as being anticipated by Thorpe et al (Biophysical J. (1995) 68:2198-2206) has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-6 under 35 USC §102(b) as being anticipated by Valenzano (Photochemistry and Photobiology (1987) 46:147-160) has been withdrawn in view of Applicant's amendment.

The rejection of claims 2-4 under 35 USC §102(b) as being anticipated by Morgan (GB 2 209 468 A) has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-4 under 35 USC §102(b) as being anticipated by Sambrook et al (Molecular Cloning, A Laboratory Manual (1989) Cold Spring Harbor: Cold Spring Harbor Laboratory Press, pages 16.30-16.31 and 16.48-16.53) has been withdrawn in view of Applicant's amendment.

The declarations under 37 CFR 1.132 filed 14 February 2002 are sufficient to overcome the rejection of claims 1-5 based upon Saito et al ((Photochemistry and Photobiology (1998) 68:745-748).

The declaration under 37 CFR 1.132 filed 14 February 2002 is sufficient to overcome the rejection of claims 1-6 based upon insufficiency of the disclosure under 35 USC §112, first paragraph.

4. Claims 1, and new claims 21-24, stand rejected under 35 USC §112, first paragraph for insufficient written description for reasons of record and as further discussed below.

Claims 1, 6 and new claims 21-24, stand rejected under 35 USC §102(b) as being anticipated by Morgan (GB 2 209 468 A).

Response to Arguments

5. With respect to the rejection of claims 1, and new claims 21-24, stand rejected under 35 USC §112, first paragraph for insufficient written description, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that the elements recited in claim 1 are fully described in the specification. This is not persuasive as the issue is not simply the individual agents or stimuli disclosed in the specification but the operable combinations of them. The number of possible combinations of agent and stimulus is extremely large. For instance, the specification teaches 9 types of stimulus and 11 types of agents. This yields 99 combinations to be tested. The specification further teaches that combinations of the agents and/or the stimuli may also be used. If one is to combine two stimuli, there are 36 possible combinations of stimuli. Two stimuli combinations times one of the 11 agents yields 396 combinations to be tested. If one is to combine two agents, there are 57 possible combinations of agents. Two agent combinations times one of the 9 stimuli yields 513 combinations to be tested. Two agent combinations times two stimuli combinations yields 2052 combinations to be tested. This sums to 3060 individual combinations that need to be tested. It is important to further note that each of the nine stimuli and 11 agents are in fact classes; for instance photosensitizers is one of the stimulus. There are 5 photosensitizers disclosed in the specification; it is likely there are many more. It is also important to note that for each combination, one will have to test a series of concentrations of agent and degrees of stimulation. Thus the numbers of combinations to be tested calculated above is actually

Art Unit: 1636

a very low underestimate when one considers the actual number of specific agents and specific stimuli taught by the specification and encompassed by the claims, as well as the series of concentrations and degrees of stimulation one would have to test within a given combination. Furthermore, the specification provides no specific guidance on what combinations are most likely to be operable or what concentrations and degrees of stimulus exposure will most likely be operable. There is only one species disclosed, terthiophene (BAT) and argon laser light. This single species is not a representative number for the number of species encompassed by the genus. The rejection is maintained.

6. With respect to the rejection of claims 1, 6 and new claims 21-24, under 35 USC §102(b) as being anticipated by Morgan (GB 2 209 468 A), Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that the technique taught by Morgan works only in liposomes and only when the liposomes are the same material as the membrane to be disrupted whereas the instant invention is not so constrained. This is not persuasive because it is unclear where in Morgan either of the above assertions is demonstrated. Furthermore, Morgan clearly teaches using liposomes comprising a photosensitizing agent (thus the membrane-disrupting agent is attached to a support) to fuse with cells or tissues when the liposomes contact the cells or tissues and are exposed to irradiation. As set forth in the previous action, the fusion of the liposomes to the cells indicate that there is a specific site of perforation or denaturation in the liposome. The teachings of Morgan disclose a species which thus anticipates the genus encompassed by the claims.

Art Unit: 1636

Furthermore, the pending claims do not exclude liposomes as supports. The rejection is maintained.

Conclusion

Claims 1, 6 and 21-24 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. **NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from

Art Unit: 1636

10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

May 5, 2002

DAVID GUZO
PRIMARY EXAMINER
David Guzo